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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/519,738 | 12/28/2004 | William Hunter Symonds | 41577/308355 | 9233 |

23370 7590 03/05/2008

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| FOSTER, CHRISTINE E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 03/05/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/519,738 | SYMONDS, WILLIAM HUNTER | |
| | Examiner | Art Unit | |
| | CHRISTINE FOSTER | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-8 and 10-20* is/are pending in the application.

4a) Of the above claim(s) *14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-13* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Amendment Entry*

1. Applicant's amendment, filed 2/7/08, is acknowledged and has been entered. Claims 1, 4, and 11 were amended. Claim 9 was previously canceled. Accordingly, claims 1-8 and 9-20 are pending in the application, with claims 14-20 currently withdrawn.

### *Objections/Rejections Withdrawn*

2. The objection to claim 1 and the rejections of claims 1-8 and 10-13 under § 112, 2nd paragraph as set forth in the prior Office action have withdrawn in response to Applicant's amendments thereto.

### *Claim Objections*

3. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

4. It appears that in the instant amendment the subject matter of claim 8 has been incorporated into independent claim 1. Since claim 1 now recites that the alkaline conditions are sufficient to release haem moieties without extracting inorganic iron, claim 8 fails to further limit the parent claim since it apparently only restates this limitation.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-3, 5, 8, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewetz et al. ("Factors Affecting the Specificity of the Luminol Reaction with Hematin Compounds" Anal Biochem. 1976 Apr;71(2):564-70, Applicant's IDS of 2/28/05) in view of Hixson et al. (WO 98/54578, Applicant's IDS).

Ewetz et al. teach a procedure for the assay of heme-containing enzymes and heme-containing proteins ("hematin enzymes" and "hematin compounds") by a luminol-based chemiluminescence assay (see in particular the abstract; page 564 to page 565, the first full paragraph; and pages 566-567, "Results").

The assay involves subjecting the sample containing the heme-containing compound to be assayed with 0.1 M NaOH before addition of alkaline luminol reagent (see the abstract and page 566, "Luminol Assay Procedure". This NaOH incubation results in an increase of the specificity and sensitivity of the luminol reaction with the heme moieties ("protoporphyrin compounds").

The alkaline conditions taught by Ewetz et al. involving 0.1 M NaOH are "sufficient to release the haem moiety from the analyte, and thereby from the one or more magnetic beads, but not to extract inorganic iron" from beads as claimed since the instant specification indicates that

such conditions include alkaline pH values in the range of pH 12.5-13.5 (specification, page 3); 0.1 M NaOH has a pH value of pH 13[1]. See also instant claim 2. Therefore, since the prior art alkaline conditions are identical to those employed by Applicant, the functional effects recited would necessarily flow from the prior art conditions.

The reference differs from the instantly claimed invention in that it fails to specifically teach an assay involving magnetic beads having specific binding partners for the heme-containing enzymes and proteins, and further fails to teach magnetic separation. In other words, the assay of Ewetz et al. is performed directly on the sample without any preliminary separation steps.

Hixson et al. also teach chemiluminescent methods for the detection of hemoglobin. The reference teaches that a portion of hemoglobin is normally glycosylated, and that the amount and/or proportion of glycosylated hemoglobin is an indicator of the presence or absence of diabetes (pages 1-2).

To distinguish between the different fractions of hemoglobin in a single sample, the fractions are first separated by chemical or physical means before the chemiluminescent reaction is induced (page 2, lines 18-35). For example, a binding agent selective for one of the hemoglobin forms may be bonded to a solid phase, followed by separation of the solid and liquid phases from each other. More particularly, dihydroxyboryl compound can be immobilized on a solid support in order to selectively separate glycosylated hemoglobin (page 5, lines 14-25).

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[1] pH of a 0.1 M NaOH solution:
$[H^+][OH^-] = 1.0 \times 10^{-14}$
$[H^+][0.1] = 1.0 \times 10^{-14}$
such that $[H^+] = 1 \times 10^{-13}$
$pH = -\log [H^+] = -\log[1 \times 10^{-14}] = 13$

Solid phases include paramagnetic particles, which are amenable to automated assays (page 6, line 15 to column 7, line 4).

Therefore, it would have been obvious to one of ordinary skill in the art to perform a preliminary separation step, as taught by Hixson et al., prior to the chemiluminescence reaction of Ewetz et al. because it allows separation/isolation of the glycated fraction of hemoglobin from the sample. In particular, it would have been obvious to perform this preliminary separation via use of magnetic beads having glycated hemoglobin-specific ligands immobilized thereon as taught by Hixson et al. One would be motivated to do this in order to specifically detect the glycated form of hemoglobin, which is an indicator of diabetes.

With respect to claim 3, Hixson et al. teach washing of the paramagnetic particles after magnetic separation, wherein the beads would necessarily be resuspended in the wash solution (see the paragraph bridging pages 6-7; Example 2) and also exemplify detection without an intervening separation step (Examples 1-2). Therefore, it would have been obvious to resuspend the beads in a washing solution prior to detection by the method of Ewetz et al. as exemplified by Hixson et al. Similarly, it would have been obvious to directly detect chemiluminescence without an intervening separation step as exemplified by Ewetz et al., and also for the benefit of reducing assay steps, thereby simplifying the assay and reducing time.

With respect to claim 5, Hixson et al. teach that the magnetic particles are washed after magnetic separation and prior to detection, wherein the beads would necessarily be resuspended in the wash solution in the course of washing (see the paragraph bridging pages 6-7; Example 2).

With respect to claim 8, the alkaline conditions taught by Ewetz et al. involving 0.1 M NaOH (pH 13) would be "sufficient to release haem moieties without extracting inorganic iron

from the beads" since this falls within the range of pH 12.5-13.5 that is disclosed in the instant specification as constituting suitable conditions for this purpose (specification, page 3).

With respect to claims 10 and 12, the luminol detection method of Ewetz et al. involves initial addition of luminol reagent followed by oxidant (sodium perborate) (see page 565, "Reagents"; page 566, "Luminol Assay Procedure"; and Figure 2 and legend). The amount used would necessarily be sufficient to generate a signal, since light emission was observed (Figure 2 and legend).

With respect to claim 11, although Ewetz et al. do not specifically teach that the amount of perborate is sufficient to oxidize all of the luminol, absent evidence of criticality it would have been obvious to one of ordinary skill in the art to discover the optimum or workable ranges out of the course of routine optimization. See MPEP 2144.05.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ewetz et al. in view of Hixson et al. as applied to claim 1 above, and further in view of Valkirs et al. (US 6,503,722 B1).

Ewetz et al. and Hixson et al. are as discussed above. Hixson et al. teaches a wash step (where the beads would necessarily be resuspended in the wash solution during the course of washing), but fails to teach separating the beads from the suspension after step (c) and performing detection on the separated suspension.

Valkirs et al. teaches a magnetic bead-based assay for detection of an analyte (C. *difficule* toxin A), in which after the magnetic separation is completed, the magnetic beads are dissociated and removed from the solution in order to obtain a highly concentrated preparation of the analyte

(the abstract). This makes possible a very sensitive assay since the effect of nonspecific binding to the beads is eliminated, allowing a greater amount of beads to be used in the assay so that all of the analyte present in the sample can be captured (ibid and column 20, line 32 to column 21, line 25; and especially at column 21, lines 10-17).

Therefore, it would have been obvious to one of ordinary skill in the art to remove the magnetic beads from the solution after magnetic separation in the method of Ewetz et al. and Hixson et al. and to perform the detection method on the bead-free suspension as taught by Valkirs et al. One would be motivated to do this in order to reduce the effect of nonspecific binding, allowing more beads to be used so that all of the glycated hemoglobin in the sample could be captured on the beads, thus increasing the assay sensitivity.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ewetz et al. in view of Hixson et al. as applied to claim 1 above, and further in view of Wang et al. (US 5,431,793).

Ewetz et al. and Hixson et al. are as discussed above. Hixson et al. teaches boronic acid ligands that are immobilized on the solid phase for selectively isolating glycated hemoglobin. However, the reference fails to specifically teach immobilized ligands for glycated hemoglobin that are *antibodies or binding fragments thereof.*

Wang et al. teach methods for measuring glycated hemoglobin in a sample, and in particular the amount of the Hb A1c form of glycated hemoglobin (column 1, line 19 to column 2, line 3). The amount of Hb A1c in blood is related to time-averaged glucose concentration, thereby providing a way of assessing the control of diabetes (column 1, lines 55-63; column 7,

lines 20-37). Wang et al. teach that the Hb A1c form can be determined in a sample containing other forms of hemoglobin using an antibody that specifically binds this form (column 3, lines 40-65). Antigen binding fragments are also contemplated (column 6, lines 42-44).

Therefore, it would have been obvious to one of ordinary skill in the art to substitute the antibody or binding fragment thereof that is specific for glycated hemoglobin of Wang et al. for the boronic acid ligands of Hixson et al. One would be motivated to do this based on the art-recognized suitability of anti-Hb A1c antibodies for the purpose of specifically binding glycated hemoglobin, which is the same purpose for which the boronic acid ligands are employed by Hixson et al.

9. Claims 1-2, 4, 6-8, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruno et al. ("Immunomagnetic-Electrochemiluminescent Detection of Bacillus anthracis Spores in Soil Matrices" Appl Environ Microbiol. 1996 Sep;62(9):3474-3476) in view of Valkirs et al., Giaever et al. (US 3,970,518) and Heroux et al. (US 2002/0146722 A1).

Bruno et al. teach methods for detecting *Bacillus anthracis* spores, which contain heme as indicated in the present application (see, e.g., claim 7), comprising the steps of (a) contacting soil suspensions with magnetic beads having immobilized thereon Gt 578 capture antiserum specific for *B. anthracis* spores; (b) separating the beads from the sample by immunomagnetic separation; and (d) detecting the analyte by electrochemiluminescence (ECL) assay (see especially the abstract and page 3474). The ECL assay employs a ruthenium(II) trisbipyridine-based label (see page 3474, the paragraph bridging the right and left columns to right column, second paragraph).

The teachings of Bruno et al. differ from the instantly claimed invention in that the reference fails to specifically teach (c) subjecting the beads to alkaline conditions sufficient to release heme moieties from the beads. The reference also teaches electrochemiluminescence assay using a ruthenium(II) trisbipyridine-based label but fails to specifically teach an assay that employs luminol.

Valkirs et al. is as discussed above, which teaches a magnetic bead-based assay for detection of an analyte (C. *difficule* toxin A), in which after the magnetic separation is completed, the magnetic beads are dissociated and removed from the solution in order to obtain a highly concentrated preparation of the analyte (the abstract). This makes possible a very sensitive assay since the effect of nonspecific binding to the beads is eliminated, allowing a greater amount of beads to be used in the assay so that all of the analyte present in the sample can be captured (ibid and column 20, line 32 to column 21, line 25; and especially at column 21, lines 10-17).

Giaever et al. also relates to immunomagnetic separation methods, in which bacteria and other analytes can be captured on antibody-bearing magnetic particles (see especially column 1, lines 35-55 and column 2, line 8 to column 3, line 20). The reference teaches that following the capture, separation, and wash steps, the captured analytes may be cleaved from the magnetic particles by use of a cleaving agent (column 2, line 66 to column 3, line 20). Suitable cleaving agents are alkaline solutions of pH 9-13 (column 3, lines 14-18).

In light of the teachings of Valkirs et al., it would have been obvious to one of ordinary skill in the art to perform a dissociation step to remove the magnetic beads from the captured spores in the method of Bruno et al. prior to ECL detection, so as to allow increased sensitivity in

the assay. In dissociating the captured spores, the heme moieties contained therein would also necessarily be released as well.

It would have been further obvious to select known means of dissociating captured analytes from magnetic beads when performing this dissociation step. In particular, it would have been obvious to subject the magnetic beads to alkaline solutions of pH 9-13 as taught by Giaever et al., based on their art-recognized suitability for this same purpose. Since the prior art conditions overlap those claimed instantly as being sufficient to release the haem moiety without extracting inorganic iron (see claim 2), it would have been obvious to arrive at the claimed invention out of the course of routine optimization when employing the alkaline conditions of Giaver et al.

Heroux et al. teach electrochemiluminescent (ECL) labels, including both ruthenium(II) trisbipyridine-based labels (as taught in Bruno et al.) and luminol [0048]. Therefore, although Bruno et al. exemplify the use of $Ru(bpy)_3^{2+}$ as the ECL label, it would have been obvious to substitute luminol as the ECL label based on its art-recognized suitability for the same purpose.

***Response to Arguments***

10. Applicant's arguments filed 2/7/08 have been fully considered.

11. With respect to the rejections of claims 1-3, 5, 8, and 10-12 under § 103(a) as being unpatentable over Ewetz et al. in view of Hixson et al., Applicant argues that the instant amendments to claim 1--to recite that the alkaline conditions release haem moieties from an analyte without extraction of inorganic iron--render the claims non-obvious over the prior art (Reply, pages 6-8).

This is not found persuasive because Ewetz et al. teach alkaline conditions of pH 13, which is within the pH range disclosed by Applicant as being suitable to achieve these effects (see claim 2 and the instant specification at page 3). Since the conditions taught by Ewetz et al. are indistinguishable from those employed by Applicant, the prior art conditions would also necessarily have the effects recited.

Similarly, in response to applicant's argument that neither Ewetz et al. nor Hixson et al. addresses the problem of iron release, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant further argues for common knowledge to those of ordinary skill in the art that luminol chemiluminescent procedures are very sensitive to inorganic iron contamination and refers to the instant specification (Reply, page 7, last paragraph). Applicant further argues that therefore, "one of ordinary skill in the art would be directed to **actively avoid combining** alkaline conditions to release haem moieties **and** magnetic bead capture because it leads to inorganic iron contaminants that can produce false negative or false positive results in a luminol chemiluminescent assay" (ibid, emphasis in original).

Initially, it is noted that Applicant's statements that the combination of alkaline conditions and magnetic bead capture "leads to inorganic iron contaminants" are not fully understood as they appear to be in direct contrast to the functional language recited in claim 1 and arguments elsewhere in the Reply. It appears that Applicant may have intended to argue that

one of ordinary skill in the art would have *expected* the combination to lead to contaminants, but that this in fact does not actually occur.

Applicant argues in essence that one of ordinary skill in the art would have expected alkaline conditions to release inorganic iron from magnetic beads to such a degree so as to interfere with luminol assay, such that one skilled in the art would not have been motivated to combine magnetic bead separation with luminol assay and would not expect success in so doing.

The Examiner has considered such arguments but finds that there is insufficient evidence to support Applicant's position that the common knowledge in the art would have led the skilled artisan away from the combination.

Once a prima facie case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the prima facie case. MPEP 2145. In the instant case, the reference to a possible technical problem that a person of ordinary skill in the art might have thought would arise (but one which apparently does not) does not constitute sufficient substantive evidence that would establish a lack of expectation of success in combining the teachings of the references.

The specification at page 1, line 28 to page 2, line 9 refers to a non-patent literature publication by Yuan et al. purported to show that Fe(III) interferes with light emitted in a luminol assay. However, this finding is not commensurate with the common knowledge being argued for by Applicant, since it is not clear whether Yuan et al. investigated Fe(III) released from magnetic beads in response to alkaline conditions. To say that it was known that Fe(III) can interfere with luminol assay is not the same as to say that it was known that Fe(III) was known to be released from magnetic beads in response to alkaline conditions (and to such a degree as to

potentially interfere with a luminol assay). Furthermore, since the Yuan et al. publication has not been made of record, any evidence therein cannot be fully evaluated.

Finally, Applicant is reminded that the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.").

Therefore, the failure of the cited prior art references to address the problem of extraction of inorganic iron from magnetic beads does not in itself support a determination of non-obviousness, since it is not apparent that this possible problem (which apparently does not actually occur) was in fact well known to the person of ordinary skill in the art. Therefore, the fact that the prior art references do not address this problem does not in and of itself support a determination of non-obviousness.

For these reasons, the Examiner finds insufficient evidence of record to support Applicant's position that one of ordinary skill in the art would have expected inorganic iron to be extracted from magnetic beads under alkaline conditions, and furthermore to therefore interfere with luminol chemiluminescent procedures. Therefore, the rejection is maintained for reasons of record because the evidence of non-obviousness fails to outweigh the evidence of obviousness.

12. With respect to the rejection of claim 4 under § 103(a) as being unpatentable over Ewetz et al. in view of Hixson et al. and Valkirs et al., Applicant argues that Valkirs et al. fail to address the problem of iron release from magnetic beads (Reply, page 8).

This is not found persuasive since as above, the fact that the prior art fails to refer to a possible technical problem that might have arisen (but apparently did not) does not in and of itself support a determination of non-obviousness. Furthermore, the alkaline conditions taught by Ewetz et al. would necessarily have the functional effects recited instantly. The fact that Applicant has recognized another advantage that would necessarily flow from the teachings of the prior art cannot serve as the basis for patentability.

Applicant further argues that Valkirs et al. provides no motivation or teaching to derive the claimed method, to which the Examiner disagrees for reasons of record as set forth above and in the prevous Office action on page 10.

Applicant further argues that based on the prior art and common knowledge of one of ordinary skill in the art, one of ordinary skill in the art would not have been motivated to combine magnetic bead capture with alkaline conditions out of concern for interference produced by inorganic iron contaminants released from the beads (Reply, page 8). This is not found persuasive because as discussed further above, there is insufficient evidence of record to establish that such concerns were well known in the art such that a reasonable expectation of success in combining the reference teachings would have been lacking. Therefore, it is maintained for reasons of record that it would have been obvious to arrive at the claimed invention with a reasonable expectation of success.

13. With respect to the rejection of claim 13 under § 103(a) as being unpatentable over Ewetz et al. in view of Hixson et al. and Wang et al., Applicant argues that Wang et al. fails to address the problem of iron release (Reply, page 9). This is not found persuasive for the reasons discussed above.

Applicant further argues that Wang et al. provides no motivation or teaching, to which the Examiner disagrees for reasons of record as set forth in the previous Office action on page 11. Furthermore Applicant is reminded that there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art. Motorola, Inc. v. Interdiqital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

14. With respect to the rejections of claims 1-2, 4, 6-8 and 13 under § 103(a) as being unpatentable over Bruno et al. in view of Valkirs et al., Giaver et al., and Heroux et al.,Applicant argues as above that none of the cited references provide a motivation, teaching or suggestion to release haem moieties from an analyte while avoiding extraction of inorganic iron from magnetic beads (Reply, pages 9-10). This is not found persuasive for similar reasons as discussed above. In particular, in the instant case the alkaline conditions taught by Giaver et al. would necessarily have the same functional effects recited instantly. Furthermore, since there is insufficient evidence of record to establish that the problem of extraction of inorganic iron from magnetic beads was well known to the person or ordinary skill in the art, the fact that the prior art references do not address this problem does not in and of itself support a determination of non-obviousness.

***Conclusion***

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine Foster/
Examiner, Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641